

CLAIMS

1. A method for determining a human's capacity to metabolize a substrate of a CYP2D6 enzyme, said method comprising the steps of:

- 5 a) isolating single stranded nucleic acids from the human, said nucleic acids encoding 5' flanking regions of *CYP2D6* genes present on each homologous chromosome 22 of the human, wherein said region is represented by a sequence as set forth in SEQ ID NO:2; and
- 10 b) detecting at least three polymorphisms within the region, wherein the polymorphisms are selected from the group consisting of nucleotides present at polymorphic sites represented by positions 36, 194, and 942 of SEQ ID NO:2; nucleotides present at polymorphic sites represented by positions 36, 620, and 942 of SEQ ID NO:2; nucleotides present at polymorphic sites represented by positions 36, 194, and 880 of SEQ ID NO:2; nucleotides at polymorphic sites represented by positions 36, 620, and 880 of SEQ ID NO:2; nucleotides at polymorphic sites represented by positions 36, 194, 620, and 880 of SEQ ID NO:2; nucleotides at polymorphic sites represented by positions 36, 194, 620, and 942 of SEQ ID NO:2; nucleotides at polymorphic sites represented by positions 36, 620, 880, and 942 of SEQ ID NO:2; and nucleotides at polymorphic sites represented by positions 36, 194, 620, 880, and 942 of SEQ ID NO:2.

- 25 2. A sequence determination oligonucleotide suitable for detecting polymorphic sites in a 5' flanking region of a *CYP2D6* gene, said oligonucleotide comprising a sequence selected from the group consisting of SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, SEQ ID NO:8, SEQ ID NO:9, SEQ ID NO:10, SEQ ID NO:11, SEQ ID NO:12, SEQ ID NO:13, SEQ ID NO:14, SEQ ID NO:15, SEQ ID NO:16; SEQ ID NO:36, SEQ ID NO:37, SEQ ID NO:38, SEQ ID NO:39, SEQ ID NO:40, SEQ ID NO:41, SEQ ID NO:42, SEQ ID NO:43, SEQ ID NO:44, SEQ ID NO:45, SEQ ID NO:46, SEQ ID NO:47, SEQ ID NO:48, SEQ ID NO:49, SEQ ID NO:50, SEQ ID NO:51, SEQ ID NO:52, SEQ ID NO:53,
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SEQ ID NO:54, SEQ ID NO:55, SEQ ID NO:56, SEQ ID NO:57, SEQ ID NO:58,
SEQ ID NO:59, SEQ ID NO:60, SEQ ID NO:61, SEQ ID NO:62, SEQ ID NO:63,
SEQ ID NO:64, SEQ ID NO:65, SEQ ID NO:66, SEQ ID NO:67, SEQ ID NO:68,
SEQ ID NO:69, SEQ ID NO:70, SEQ ID NO:71, SEQ ID NO:72, SEQ ID NO:73,
5 SEQ ID NO:74, SEQ ID NO:75, SEQ ID NO:76 and SEQ ID NO:77.

3. An oligonucleotide primer pair suitable for amplifying a 5' flanking
region of a *CYP2D6* gene, said primer pair having sequences selected from the
group consisting of: SEQ ID NO:17 and SEQ ID NO:18; SEQ ID NO:19 and SEQ
10 ID NO:20; SEQ ID NO:21 and SEQ ID NO:22; SEQ ID NO:23 and SEQ ID NO:24;
SEQ ID NO:25 and SEQ ID NO:26; SEQ ID NO:27 and SEQ ID NO:28; SEQ ID
NO:29 and SEQ ID NO:30; SEQ ID NO:31 and SEQ ID NO:32; SEQ ID NO:33
and SEQ ID NO:34; and SEQ ID NO:35 and SEQ ID NO:18.

15 4. A kit comprising at least three oligonucleotide primer pairs suitable
for amplification of polymorphic regions corresponding to positions 36, 194, and
942 of SEQ ID NO:2; or at least three oligonucleotide primer pairs suitable for
amplification of polymorphic regions corresponding to positions 36, 194, and 880 of
SEQ ID NO:2; or at least three oligonucleotide primer pairs suitable for
20 amplification of polymorphic regions corresponding to positions 36, 620, and 942 of
SEQ ID NO:2; or at least three oligonucleotide primer pairs suitable for
amplification of polymorphic regions corresponding to positions 36, 620, and 880 of
SEQ ID NO:2.

25 5. The kit of claim 4, wherein the primer pairs are suitable for
amplification of polymorphic regions corresponding to positions 36, 194, and 942 of
SEQ ID NO:2; further comprising:

i) a sequence determination oligonucleotide comprising a sequence
selected from the group consisting of SEQ ID NO:3; SEQ ID NO:10; SEQ ID
30 NO:36; SEQ ID NO:37; SEQ ID NO:50; SEQ ID NO:57; SEQ ID NO:64; and SEQ
ID NO:71;

ii) a sequence determination oligonucleotide comprising a sequence
selected from the group consisting of SEQ ID NO:4; SEQ ID NO:11; SEQ ID

NO:38; SEQ ID NO:39; SEQ ID NO:51; SEQ ID NO:58; SEQ ID NO:65; and SEQ ID NO:72; and

- iii) a sequence determination oligonucleotide comprising a sequence selected from the group consisting of SEQ ID NO:8; SEQ ID NO:15; SEQ ID NO:46; SEQ ID NO:47; SEQ ID NO:55; SEQ ID NO:62; SEQ ID NO:69; and SEQ ID NO:76.

6. The kit of claim 4, wherein the primer pairs are suitable for amplification of polymorphic regions corresponding to positions 36, 194, and 880 of SEQ ID NO:2; further comprising:

- i) a sequence determination oligonucleotide comprising a sequence selected from the group consisting of SEQ ID NO:3; SEQ ID NO:10; SEQ ID NO:36; SEQ ID NO:37; SEQ ID NO:50; SEQ ID NO:57; SEQ ID NO:64; and SEQ ID NO:71;
- ii) a sequence determination oligonucleotide comprising a sequence selected from the group consisting of SEQ ID NO:4; SEQ ID NO:11; SEQ ID NO:38; SEQ ID NO:39; SEQ ID NO:51; SEQ ID NO:58; SEQ ID NO:65; and SEQ ID NO:72; and
- iii) a sequence determination oligonucleotide comprising a sequence selected from the group consisting of SEQ ID NO:7; SEQ ID NO:14; SEQ ID NO:44; SEQ ID NO:45; SEQ ID NO:54; SEQ ID NO:61; SEQ ID NO:68; SEQ ID NO:75.

7. The kit of claim 4, wherein the primer pairs are suitable for amplification of polymorphic regions corresponding to positions 36, 620, and 942 of SEQ ID NO:2; further comprising:

- i) a sequence determination oligonucleotide comprising a sequence selected from the group consisting of SEQ ID NO:3; SEQ ID NO:10; SEQ ID NO:36; SEQ ID NO:37; SEQ ID NO:50; SEQ ID NO:57; SEQ ID NO:64; and SEQ ID NO:71;
- ii) a sequence determination oligonucleotide comprising a sequence selected from the group consisting of SEQ ID NO:6; SEQ ID NO:13; SEQ ID

NO:42; SEQ ID NO:43; SEQ ID NO:53; SEQ ID NO:60; SEQ ID NO:67; SEQ ID NO:74; and

- iii) a sequence determination oligonucleotide comprising a sequence selected from the group consisting of SEQ ID NO:8; SEQ ID NO:15; SEQ ID NO:46; SEQ ID NO:47; SEQ ID NO:55; SEQ ID NO:62; SEQ ID NO:69; and SEQ ID NO:76.

8. The kit of claim 4, wherein the primer pairs are suitable for amplification of polymorphic regions corresponding to positions 36, 620, and 880 of SEQ ID NO:2; further comprising:

i) a sequence determination oligonucleotide comprising a sequence selected from the group consisting of SEQ ID NO:3; SEQ ID NO:10; SEQ ID NO:36; SEQ ID NO:37; SEQ ID NO:50; SEQ ID NO:57; SEQ ID NO:64; and SEQ ID NO:71;

- ii) a sequence determination oligonucleotide comprising a sequence selected from the group consisting of SEQ ID NO:6; SEQ ID NO:13; SEQ ID NO:42; SEQ ID NO:43; SEQ ID NO:53; SEQ ID NO:60; SEQ ID NO:67; SEQ ID NO:74; and

- iii) a sequence determination oligonucleotide comprising a sequence selected from the group consisting of SEQ ID NO:7; SEQ ID NO:14; SEQ ID NO:44; SEQ ID NO:45; SEQ ID NO:54; SEQ ID NO:61; SEQ ID NO:68; SEQ ID NO:75.

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